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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/629,424 | 07/29/2003 | Frieder Braunschweig | P10978.00 | 6026 |

27581 7590 08/10/2006

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| EXAMINER | |
|---|---|
| PATEL, NATASHA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3766 | |

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/629,424 | BRAUNSCHWEIG ET AL. | |
| | Examiner | Art Unit | |
| | Natasha N. Patel | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *1,2,4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Clarification of the monitoring functions of the monitoring and/or stimulating means.

### *Claim Objections*

2. Claims 1, 2, and 4 are objected to because of the following informalities: The claim language for "a hemodynamic monitor means" does not come under the purview of 35 USC§ 112, sixth paragram. Appropriate correction is required. It is suggested that these claims be rewritten to read "a means for collecting hemodynamic data".

### *Claim Rejections - 35 USC § 112*

3. Claims 1, 3, 5, 7, 9, 10, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The monitoring aspect of the monitoring and/or stimulating device is not expressly disclosed. The plurality of the means for monitoring makes it difficult to determine enablement.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being obvious over Kieval et al. (US Patent 5,626,623) in view of Carlson (US Patent 6,026,324).

6. Regarding Claim 1, Kieval discloses a system for collecting hemodynamic data from a patient (see col. 3, lines 42-44) and utilizing said data to optimize a cardiac pacing regimen for said patient (see col. 4, lines 10-13), comprising: a hemodynamic monitor means (see absolute pressure sensor 160 and microcomputer 302) for continuously (see col. 16, line 21) collecting hemodynamic data (see col. 3, lines 42-44) of a patient and for storing said collected hemodynamic data (see RAM/ROM 310, 312, 314), a means for monitoring and/or stimulating cardiac tissue (see IPG 100) of a patient to provide or restore a desired cardiac rhythm (see col. 4, lines 40-43), and a means for integrating at least a portion of the collected hemodynamic data with the means for monitoring and/or stimulating cardiac tissue to optimize one or more hemodynamic characteristics of said patient (see col. 17, lines 34-54). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Furthermore, the examiner considers that the hemodynamic data (RVP signal) is integrated into the pulse generator's pacing program to establish an optimal AV delay (see col. 17, lines 25-29), which consequently optimizes a hemodynamic characteristic of the patient. Although Kieval mentions activity levels (see col. 10, lines 41-42) and periods of rest (see col. 10, line 64), Kieval does not explicitly disclose that hemodynamic data is

collected during both activity and rest. However, Carlson discloses a similar optimization system, in which the monitoring means (accelerometer 16) collects pulse pressure data (see col. 4, line 64) during periods of rest (see col. 2, line 66- col. 3, line 7) and periods wherein said patient is performing the activities of daily living (see col. 5, lines 6-8). It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods of rest and during activity because Carlson teaches the benefit of being able to differentiate between activity and rest, thereby providing an appropriate AV delay (see col. 7, lines 10-34).

7. Regarding Claim 2, Kieval discloses that the hemodynamic monitor means is an absolute pressure sensor (see col. 8, lines 19-21) adapted to be fluidly coupled to a cardiac chamber of the patient (see Figure 4). The examiner considers that sensor 160 on lead 114 has the ability to be fluidly coupled. Furthermore, it has been held that the recitation that an element is "adapted to" perform function in not a positive limitation in any patentable sense (*In re Hutchinson*, 60 USPQ 138).

8. Regarding Claim 3, Kieval discloses that the means for monitoring and/or stimulating comprises a pulse generator (see col. 7, lines 54-55 and Figure 4).

9. Regarding Claim 4, see rejection of similarly worded Claim 2 above. As to the activity level measurement means, Kieval discloses an activity sensor 316 optionally coupled to the IPG housing (see col. 10, line 36), thereby coupled to the patient, said activity-level measurement means is derived from a piezoelectric crystal transducer (see col. 10, line 38). Kieval does not disclose that the output signal of said activity-level measurement means is time-synchronized to the hemodynamic monitor means. Carlson

discloses that the activity-level output and the hemodynamic monitor output signals in a time-synchronized fashion (see col. 7, lines 10-12). The examiner considers that the activity level measurement means accelerometer 50) must output a signal at the same time the hemodynamic monitor (accelerometer 16) outputs a signal to the microprocessor if the level of physical activity is to be a portion of the hemodynamic signal. It would be obvious to one of ordinary skill in the art at the time of the invention to synchronize the output of the activity level measurement means to the hemodynamic monitor means so the activity level can be easily correlated to the hemodynamic status of the heart and an appropriate AV delay can be determined (see col. 7, lines 10-34).

10. Regarding Claim 6, Kieval discloses that the hemodynamic data is a pressure signal sensed in the right ventricle (see col. 3, lines 42-44).

11. Regarding Claim 7, Kieval discloses that the hemodynamic data is collected at a pre-determined time of day and at a pre-determined interval (see col. 17, lines 34-38 and lines 66-67). The examiner considers since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day, hemodynamic data is also collected at pre-determined times of the day.

12. Regarding Claim 8, Kieval discloses that during the providing step an A-V interval (see col. 17, lines 52-54) comprises a part of the cardiac stimulation sequence. The examiner considers that the main goal of the AV optimization method is to provide an optimized AV interval to the cardiac pacing regime so an AV interval must be provided to the cardiac stimulation sequence (see col. 4, lines 40-43).

13. Regarding Claim 9, Kieval does not disclose a bi-ventricular device. However, Carlson teaches that the method of optimizing a pacing regime could apply to a variety of different devices, including a bi-ventricular device (see V-V pacing; col. 2, lines 13-16).

14. Regarding Claim 10, Kieval and Carlson both disclose a dual-chamber pacing mode (see Kieval, Figure 4 and col. 7, lines 54-55; see Carlson, col. 3, lines 18-19).

15. Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

16. Regarding Claim 13, Kieval discloses that the cardiac stimulation sequence comprises data based at least in pad on the lowest estimated pulmonary artery diastolic pressure measured during collection of the hemodynamic data (see col. 3, lines 53-57).

17. Regarding Claims 5 and 14, Kieval discloses a method of optimizing hemodynamics of a patient (see col. 4, lines 10-13) having an implantable cardiac rhythm stimulation and monitoring device (see IPG circuit 300), comprising the steps of: collecting hemodynamic data from said patient (see col. 3, lines 42-44) with a hemodynamic monitor (see absolute pressure sensor 160 and microcomputer 302)

adapted to be disposed in fluid contact with a volume of venous blood of said patient (see col. 5, lines 59-61). The examiner considers since the pressure sensor 160 is in the right ventricle and the venous blood enters the right ventricle, then the pressure sensor 160 is in fluid contact with the venous blood. Kieval discloses storing said collected hemodynamic data (see RAM/ROM 310, 312, 314). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Kieval further discloses collecting cardiac event data from the patient (see col. 15, lines 40-46 and Figures 5 and 10) and storing the cardiac event data in a computer readable memory medium (see RAM/ROM 310, 312, 314). The examiner considers that although the ECG is stored in memory after it has already been processed, the ECG is still being stored in some way, shape, or form. Carlson similarly discloses collecting hemodynamic data and electrograms, which contain cardiac event data, and storing the data so it can be analyzed (see col. 4, lines 52-58). Kieval and Carlson disclose analyzing said hemodynamic data in conjunction with said cardiac event data to determine a cardiac stimulation sequence intended to optimize the hemodynamics of said patient, and providing said cardiac stimulation sequence to an implantable cardiac rhythm stimulation and/or monitoring device (see Kieval, col. 17, lines 34-54; see Carlson, col. 4, lines 52-58 and Figure 1). Kieval does not disclose collecting hemodynamic data and electrograms during activity levels above resting rate. Carlson discloses performing this collection process during a period of time when a heart rate of the patient is elevated above a resting rate due to activity by said patient (see col. 5, lines 6-8). The examiner

considers that if low activity levels are being identified, then there must be a range of activity levels from which the low activity level can be identified and at least one of these levels must be elevated above a resting rate. It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods activity because a patient will not always be at rest and Carlson teaches the benefit of being able to provide an appropriate AV delay at any activity level (see col. 7, lines 10-34).

18. Regarding Claim 14, see rejection of similarly worded Claim 5 above. As to a computer readable medium, Kieval and Carlson both disclose some type of instructions for performing this optimization method (see microcomputer 302 in Kieval, col. 9, line 64- col. 10, line 32; see microprocessor 18 in Carlson, col. 4, lines 52-58).

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
8/4/06

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766